REMARKS

Claims 1, 3-5, 16-20 and 22-34 are presently pending. Of these, Claims 16-20, 22 and 23 are withdrawn from consideration. Support for claim amendments and new Claims 28-34 is discussed below. No new matter has been added herewith. The following addresses the substance of the Office Action.

Enablement

Claims 1, 3-5 and 24-27 were rejected under 35 U.S.C. § 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. In particular, the Examiner stated that omitted steps are: 1) the buffer conditions for selectively eluting fibrinogen off of the column, 2) the buffer conditions for separately eluting plasminogen off of the column, and 3) the metal ion of the immobilized metal ion affinity chromatography matrix.

The Applicants have amended the claims to recite the buffer conditions for separately eluting plasminogen and fibrinogen, and to recite the metal ions of the affinity chromatography matrix. Examples of support for the various claim amendments and for new Claims 28-34 is found in the Specification as filed as follows:

Claim(s)	Amendment	Support
1 and 3	"wherein the immobilized metal ion affinity chromatography matrix is a copper, nickel or zinc ion affinity chromatography matrix"	Page 5, lines 35-36
1	"wherein plasminogen is eluted using a buffer comprising a low concentration of a low molecular weight competitive chelating compound, a reduced pH compared to the loading solution, or a reduced ionic strength compared to the loading solution, wherein fibrinogen remains bound"	Page 6, lines 30-34 and page 6, lines 28-34
1	"wherein fibrinogen is eluted using a buffer comprising a higher concentration of the same or a different low molecular weight competitive chelating compound, a reduced pH compared to the loading solution or the buffer used to elute plasminogen, or a reduced ionic strength compared to the loading solution or the buffer used to elute plasminogen"	Page 7, lines 11-13 and page 6, lines 28-34

Claim(s)	Amendment	Support
1, 3 and 4	"wherein the competitive chelating compound is selected from the group consisting of an amino acid, imidazole, EDTA and a citric salt"	Page 6, lines 35-37
3	"wherein the fibrinogen is eluted using a buffer comprising more than 20 mM of a competitive chelating compound, a reduced pH compared to the loading solution, or a reduced ionic strength compared to the loading solution"	Page 7, lines 11-13, Page 7, lines 17-19, and page 6, lines 28-34
4	"wherein plasminogen is eluted using a buffer comprising ≤20 mM of a competitive chelating compound, a reduced pH compared to the loading solution, or a reduced ionic strength compared to the loading solution"	Page 7, lines 5-8, and page 6, lines 28-34
28	New Claim	Page 7: lines 5-8 and lines 17-19
29	New Claim	Page 7: lines 8-10 and 14-16
30	New Claim	Page 7: lines 8-10
31	New Claim	Page 7, lines 14-16
32	New Claim	Examples: (e.g., pages 17-18, Example 5, pages 19-20, Example 9, pages 22-23, Example 11, pages 25-26, Example 12, and pages 31-32, Example 15)
33	New Claim	Page 32, Table 10
34	New Claim	Page 17-18: Example 5

As recited in the amended claims, in some embodiments, plasminogen is eluted with a low concentration of a low molecular weight competitive chelating compound, and fibrinogen is eluted with a higher concentration of the same or a different low molecular weight competitive chelating compound, wherein the competitive chelating compound(s) are amino acid(s), imidazole, EDTA or a citrate salt.

With regard to buffer concentrations and pH, the skilled person would know, or be able to readily determine in the light of the common general knowledge in the field, how pH and buffer conditions affect the elution of blood proteins. See for example column 6, lines 43-60 of U.S. Patent No. 5,445,958 (submitted herewith along with and Information Disclosure Statement), which describe how pH and ionic strength affect elution of various blood proteins. In any event,

the skilled person would know that proteins are stable over a given pH range. For example, it is well known that fibrinogen is stable in the pH range of from about 5-9 so a skilled person would not use a pH outside this range for fear of damaging the desired product. Furthermore, commercially available immobilized metal ion affinity chromatography columns are typically supplied with instructions detailing the suitable pH ranges over which the columns may be used.

Turning to ionic strength, Page 6, line 26 through page 7, line 23 provide the skilled person with enough teaching to be able to optimize buffer conditions for the separate elution of plasminogen and fibrinogen. In particular, these paragraphs teach the skilled person that plasminogen binds less tightly than fibrinogen, that when both proteins are bound, plasminogen can be eluted by using a low concentration of chelator, and that fibrinogen can subsequently be eluted using a higher concentration of chelator. These paragraphs also identify a range of metal chelate matrices which can be used. It would be readily understood by a skilled person that other buffering salts would be chosen to minimize protein damage and optimize the binding/elution characteristics of the matrix.

In view of the amendments to the claims and the foregoing remarks, the claims contain all of the essential steps and are complete. Accordingly, the claims are in compliance with the requirements of 35 U.S.C. § 112, second paragraph. As such, the Applicants respectfully request that the rejection be withdrawn.

Anticipation

Claim 11 was rejected under 35 U.S.C. § 102(b) as being anticipated by WO 95/25748). The Examiner stated that the reference teaches purified fibrinogen and that determination of patentability is based on the product itself and not on its method of production. Without acquiescing, the Applicants have canceled Claim 11, solely to expedite prosecution. Accordingly, the Applicants respectfully request that the rejection under 35 U.S.C. § 102(b) be withdrawn.

No Disclaimers or Disavowals

Although the present communication may include alterations to the application or claims, or characterizations of claim scope or referenced art, Applicant is not conceding in this application that previously pending claims are not patentable over the cited references. Rather,

any alterations or characterizations are being made to facilitate expeditious prosecution of this application. Applicant reserves the right to pursue at a later date any previously pending or other broader or narrower claims that capture any subject matter supported by the present disclosure, including subject matter found to be specifically disclaimed herein or by any prior prosecution. Accordingly, reviewers of this or any parent, child or related prosecution history shall not reasonably infer that Applicant has made any disclaimers or disavowals of any subject matter supported by the present application.

Co-Pending Applications of Assignee

Applicant wishes to draw the Examiner's attention to the following co-pending applications of the present application's assignee.

Docket No.	Serial No.	Title	Filed
FDEHN7.001APC	10/520457	PROCESS FOR PRODUCING A VIRUS-INACTIVATED THROMBIN PREPARATION	30-Nov-2005

CONCLUSION

In view of Applicants' amendments to the Claims and the foregoing Remarks, it is respectfully submitted that the present application is in condition for allowance. Should the Examiner have any remaining concerns which might prevent the prompt allowance of the application, the Examiner is respectfully invited to contact the undersigned at the telephone number appearing below.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: September 11, 2009

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